EXHIBIT A

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO: PRODUCTS LIABILITY LITIGATION

MDL Docket No. 1629

NO. 04-10981

SUPREME COURT OF THE STATE OF NEW YORK

COUNTY OF NEW YORK

IN RE: NEW YORK NEURONTIN PRODUCTS LIABILITY LITIGATION

CONTAINS CONFIDENTIAL INFORMATION

THIS DOCUMENT APPLIES TO:

ALL CASES

The Videotaped deposition of CYNTHIA MCCORMICK, M.D., was held on Thursday, February 14, 2008, commencing at 9:04 a.m., at the law offices of Shook, Hardy & Bacon, 600 Fourteenth Street, Northwest, Washington, D.C., before Karen Geddes, CSR, and notary public.

REPORTED BY: Karen Geddes, CSR

APPEARANCES:

ON BEHALF OF THE PLAINTIFFS:
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(APPEARANCES continued on next page.)

(APPEARANCES continued.)

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ALSO PRESENT:

Mr. Keith Altman
Mr. Vijay V. Bondada
Mr. Ari Kresch
Mr. Hans Jorgensen, The Videographer

PROCEEDINGS

THE VIDEOGRAPHER: On the record at 9:04 a.m., Thursday, February 14, 2008. This is the videotaped deposition of Dr. Cynthia McCormick taken by Mark Lanier, Esquire, with offices at 6810 Farm Market 1960 West, in Houston, Texas.

The caption in the case is in re: Neurontin Marketing Sales Practices and Products Liability Litigation MDL, Docket Number 1629 in the United States District Court, District of Massachusetts.

The deposition is being conducted in the offices of Shook Hardy & Bacon located at 600 Fourteenth Street, N.W., Washington, D.C.

I'm Hans Jorgensen, videographer for Veritext. The court reporter is Karen Geddes also with Veritext.

Would Counsel please introduce themselves.

MR. SAYLER: Scott Sayler, Shook Hardy & Bacon, representing the Pfizer Defendants.

MR. GUNTER: Vince Gunter, Shook Hardy & Bacon, for the Pfizer Defendants.

MR. BONDADA: Vijay Bondada, Pfizer Legal.

MR. FINKELSTEIN: Andrew Finkelstein, Finkelstein & Partners, product liability

Plaintiffs.

MR. LEONE: Bob Leone, Lanier Law Firm.

MR. ALTMAN: Keith Altman, non-attorney, Finkelstein & Partners.

MR. KRESCH: Ari Kresch, Finkelstein & Partners.

MR. SOH: Ken Soh, Lanier Law Firm, for the Plaintiffs.

MR. LANIER: And I'm Mark Lanier. I will be taking the deposition for the Plaintiffs.

THE VIDEOGRAPHER: Will the court reporter please swear in the Witness.

Whereupon,

CYNTHIA MCCORMICK, M.D.,

having been first duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MR. LANIER:

Q Are you Cynthia McCormick?

A Yes.

(McCormick Deposition Exhibit Number 1 was marked for identification.)

BY MR. LANIER:

Q I'm going to hand you a document, Deposition Exhibit No. 1. Did you write this safety update that was put out, I think November 2nd of

MR. LANIER: Yes or no?
THE WITNESS: -- I really believe that I -- I did answer that. And I think that you're probably asking a question -- maybe we're answering -- we're talking about two different things. I think that what I -- what I wrote down and when I wrote the review was that looking ahead that we need to watch this adverse event because it may -- it may turn out to be a problem.
Time has -- has passed and another application has been approved, another database has been reviewed, and actually, probably, a third database has been reviewed that I'm not as familiar with, and that has not turned out to be the case.
Now, I think that, you know, you can look at this FDA alert very superficially and try to make something of it, but there's a lot more here than -- than I think you are acknowledging.
So, you know, this is not a black-and-white yes or no, was I wrong then and right now? was I right then and wrong now? It's not about that. It's about this is a process in evolution. We didn't have the advantage of time in 1991 and time in the market. All we had was basically a database that consisted of controlled

information and some open-label exposure, and we got a lot of reports in the open-label exposure that really we didn't have any capacity or capability to -- to really interpret.
So I don't think that the views are inconsistent. I think you're trying to make them inconsistent, but I don't see them as inconsistent.
MR. LANIER: Objection, nonresponsive.
BY MR. LANIER:
Q Ma'am, I'm just asking a very simple question that you seem to think is more complicated than it is. My question is this: As we sit here today, do you believe that depression may become worse and require intervention or lead to suicide as a --
A In general, yes.
Q -- serious event that may limit Neurontin's widespread usefulness?
MR. SAYLER: Objection, asked and answered; it's also argumentative.
MR. LANIER: So your answer is yes?
MR. SAYLER: No, that's not what she said.
THE WITNESS: You know, I think I --
MR. LANIER: She just said yes.
THE WITNESS: I didn't say yes.

MR. SAYLER: No, she didn't say yes.
MR. LANIER: It says "In general, yes." She typed it up.
MR. SAYLER: Well, she violated your rule and said yes to a phrase within the entire question. So ask the entire question, wait until he has finished asking the question and give a response to the question.
MR. LANIER: I'm satisfied with her answers.
Or did you tell me the truth just now when you said general --
MR. SAYLER: You obviously --
MR. LANIER: Excuse me.
MR. SAYLER: No. I can make my --
MR. LANIER: Excuse me. Excuse me. Not while I'm talking. If you're making an objection, you're allowed to say objection to form or you're allowed to instruct her not to answer or you're allowed to make an objection to responsiveness. You're not allowed to sit here and coach her.
MR. SAYLER: My objection --
MR. LANIER: Y'all are paying her. She doesn't need your coaching.
MR. SAYLER: My objection for the

record is you're misstating what she has testified.
BY MR. LANIER:
Q Ma'am, I'm not misstating anything. I'm just asking you -- the court reporter has typed it up. You and I have been through the fuss. You've said you're going to answer my questions when I'm done. Are you sticking by your answer or do you need to backtrack?
A I believe I've answered it.
Q Great. Now, let's go back to Exhibit 3-A.
A Which is what?
Q That's the one you've got right in front of you. It's got that exhibit and that's where the numbers are. All right.
Am I reading this right, that "In the FDA's analysis, patients receiving antiepileptic drugs" -- have I read it right so far?
A Where are you reading from?
Q The FDA Alert.
A Yes.
Q It starts --
A That's not what I'm reading here.
Q Okay.
A "The FDA has analyzed reports --"
Q "In the FDA's analysis" --

A Thank you.
Q Do you see where that is?
A Yes, I do.
Q All right. Tell me if I'm reading right: "In the FDA's analysis, patients receiving antiepileptic drugs" -- have I read it right so far?
A Yes, you have.
Q And would you agree with me that the antiepileptic drugs being talked about in this paper include Neurontin?
A Uh-huh.
Q Is that a yes answer?
A Yes, it is.
Q All right. So "patients receiving antiepileptic drugs" -- including Neurontin, we've agreed?
A Yes.
Q Tell me if I read correctly: "had approximately" --
A No, you're not reading correctly, because it doesn't say "Neurontin" in this line.
Q That's right. But you'd --
A It doesn't say any specific drug in this line.
Q Okay. Let me backtrack because that's

what I was trying to say just now.
"Patients receiving antiepileptic drugs," I've read that portion correctly, right?
A Yes.
Q And you and I know from reading the whole paper that when they say "antiepileptic drugs" here, the FDA is including Neurontin in that, right?
A It was definitely included in the analysis.
Q So when it says "patients receiving antiepileptic drugs," they're including there Neurontin, right?
A Uh-huh.
Q Is that a yes answer?
A Yes.
Q Then, now tell me if I'm reading correctly, quote, "had approximately twice the risk of suicidal behavior or ideation --" and it gives the statistic.
MR. SAYLER: Go ahead and give the statistic.
MR. LANIER: Are you going to take the depo for me?
MR. SAYLER: No. I'm objecting to the incompleteness of just saying it gives the

statistic.
MR. LANIER: I assume you've been doing this long just by looking at your age. Okay? Yeah. Now, you and I both know that's not polite attorney etiquette to be interrupting a lawyer with this kind of stuff.
MR. SAYLER: Well, it doesn't say give the statistics --
MR. LANIER: Now, if you're hurting that bad that you need to, I'll cut you slack, but I'm not hurting you that bad yet. Wait until I cut you to start being rude.
BY MR. LANIER:
Q Okay. Now, ma'am, let me go back to what I was saying. Tell me if I'm reading this correctly, quote, "had approximately twice the risk of suicidal behavior or ideation --" Have I read it correctly so far?
A Yes. If you'd like to, you can read the whole sentence.
Q And then -- hold on. I'm breaking it apart.
A If you'd like, I can read the whole sentence.
Q That's okay. I'd like to break it apart.

I'll do this my way. Thank you, though. I appreciate the offer.
And then it gives the statistic of 0.43 percent, right?
A Yes.
Q Then it says "compared to patients receiving placebo," true?
A True.
Q Then it gives the statistic there, doesn't it?
A Yes.
Q It says, quote, "The increased risk of suicidal behavior and suicidal ideation was observed as early as one week after starting the antiepileptic drug...," doesn't it?
A Yes.
Q It says it also, quote, "continued through 24 weeks," close quote, doesn't it?
A Yes.
Q And then it says, "The results were generally consistent among the eleven drugs," doesn't it?
A Yes.
Q And again, those eleven different antiepileptic drugs include -- bless you -- include

Neurontin; isn't that true?
A True.
Q And it -- look at the last page. This says specifically, quote: The FDA expects the increased risk of suicidality is shared by all AEDs, doesn't it?
A Yes.
Q By the same token, there is more to it than we've just read, isn't there?
A Yes.
Q So we can look, for example, at page 2, right?
A Right.
Q Page 2, you see that big bold black print in the middle of the page that says "Healthcare professionals..."?
A Yes.
Q Up above it, is a paragraph that starts out with "All patients..." Do you see that?
A Yes.
Q It says, "All patients treated with antiepileptic drugs should be monitored for suicidality and other unusual changes in behavior," doesn't it?
A Yes, it does.

Q It says that "Healthcare professionals who prescribe antiepileptic drugs..." -- that'd be like Neurontin, right?
A Yes.
Q -- that they should "Balance the risk for suicidality with the clinical need for the drug," don't they?
A Yes.
Q Now, this is an FDA Alert, isn't it?
A Yes.
Q You know what an FDA Alert is, don't you?
A Yes.
Q That's an important matter that's coming out: Bam, alert, right?
A Yes.
Q And this information that we have, this reflects the FDA's current analysis of the available data, all of it, concerning these drugs, doesn't it?
A Yes.
Q Looks like you were right back in 1992, doesn't it?
A Yes.
Q All right. New subject. I want to talk to you about your qualifications and who you are. You're a medical doctor, right?

A Yes.
Q Do you practice medicine?
A No, not any longer.
Q I looked at your training. It looks to me like you're trained as a pediatrician; is that right?
A Yes.
Q That's a baby and kid doctor, right?
A (No verbal response.)
Q A yes answer?
A Yes, it is.
Q "Nods," the same problem. If we ever lose --
A I understand.
Q -- the video --
A I understand.
Q -- all right -- can't tell the difference between nodding that way and that way when she types it.
A Thank you.
Q Now, in addition to your training as a pediatrician, you worked for the FDA, didn't you?
A Yes.
Q And in the FDA, you did most of your work in new drugs?

A Yes.
Q You weren't part of the post-marketing division, were you?
A No.
Q The post-marketing division is the division in the FDA that monitors drugs after they've been approved, right?
A Correct.
Q You were in the part that just -- that worked up the approval of the drug?
A Uh-huh.
Q Is that a yes?
A Yes, it is.
Q You're not a neuropsychiatrist, true?
A That's true.
Q You're not an epidemiologist?
A That's true.
Q Epidemiologists are those numbers doctors who figure out percentages and associations based on -- on whether a study shows adequate power and things like that, right?
A Well, I don't think I would characterize it quite like that, but if that's how you understand it, that's fine.
Q Well, that's probably the way it's been

presented to the jury. The jury will hear from epidemiologists and the jury is going to hear them talking about the power of studies and associations and 95 percent degree of confidence intervals and a doubling of the risk and -- and rate ratios; those are epidemiology terms, by in large, fair?
A They are statistical terms, and yes, epidemiologists use those terms.
Q All right. You're not an epidemiologist?
A I am not an epidemiologist.
Q How much is Pfizer paying you to testify in this case?
MR. SAYLER: Objection.
MR. LANIER: Why?
MR. SAYLER: Paying her for her time.
MR. LANIER: Time testifying, right?
MR. SAYLER: Time doing whatever she's doing.
BY MR. LANIER:
Q They don't pay you to eat breakfast, do they?
A No, they don't.
Q Do they pay you to sleep?
A No, they don't.
Q Do they pay you to testify?

A I hope so.
Q Okay. So how much are they paying you to testify?
A Actually, we haven't discussed that.
Q You hadn't sent them a bill yet?
A Not for this, because we haven't finished.
Q All right. You tell them it was grueling, okay, and make them pay you.
How much are they paying you in general to work on this case?
A My usual consulting fee.
Q And what is that?
A $500 an hour.
Q And do you have a clue how much time you've spent so far?
A I have -- you've actually brought the records that you have subpoenaed, so you have those at your access. I don't -- I can't tell you right now how many hours I've spent in the past few days. It's been a few hours yesterday, six hours yesterday, roughly, and whatever time we spend today.
MR. LANIER: All right. Why don't we take a break for a minute, and let me have the documents that we need, and I'll look at those and then we'll

start back up.
THE VIDEOGRAPHER: Off the record 9:40 a.m.
(Recess 9:40 a.m. to 9:51 a.m.)
THE VIDEOGRAPHER: On the record 9:51 a.m.
BY MR. LANIER:
Q Ma'am, I got a chance to look at your bills. Looks to me like as of September 14th of '07 or so, you billed somewhere around, oh, $17,000 or so, maybe a little more. Does that seem about right?
A I -- those are the documents, so -- I haven't added it up.
Q Well, why don't we mark them as Exhibit 10 and I'll ask you, is that an accurate reflection of all of the time spent and money you've made on this case, through the time period covered by that -- those invoices?
(McCormick Deposition Exhibit Number 10 was marked for identification.)
A Some of this was reimbursed travel expenses.
BY MR. LANIER:
Q Okay. But you've got your time and your money there, don't you?

A It's not separated.
Q Okay. In addition to that, I assume you have spent some time since last September, right?
A Yes.
Q I mean, I've looked through your box of file materials and you've got the same FDA document that you read here to the jury and it's highlighted, which tells me you'd read it before, right?
A Yes.
Q Do you have -- how do you keep your time? Do you have current time entries or anything?
A Not at the moment. I keep them in a -- in a handwritten book, although I have to say I have not updated it in the past couple of weeks since this has been active.
Q You just go back and reconstruct it afterwards or something?
A I have a calendar. I know when I've been downtown, I know, roughly, you know, what time I have spent each day.
Q Don't destroy your handwritten book, please, or your calendar sheets, because I'd like to see those.
A My calendar sheet does not just contain this work.

A Uh-huh. This is actually a syndrome that follows shingles.
Q Yeah.
A But yeah, you've got the -- you've got the right idea.
Q So the FDA --
A Chronic neuropathic pain following shingles.
Q All right. Now, the advisory committee that met that we were discussing on this drug back in '92 --
A Yes.
Q -- met only to consider the risk-benefit for this portion of the epilepsy population, right?
A That's correct.
Q The approval that was ultimately given, the initial approval, was only for this subgroup within the epilepsy population, right?
A In the adults with epilepsy, yes. And in fact, specifically there is the indication -- it is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy.
Q Were you in on the label negotiations with the drug company?

A Yes.
Q Y'all never negotiated labeling for other uses for this drug beyond that epilepsy group?
A True; not at this time.
Q Now, the FDA never did any of its own studies?
A That's correct.
Q The FDA has always relied on the drug company for the actual studies of the drug Neurontin, right?
A I believe so. Occasionally, the FDA will conduct its own studies, but I don't believe in this case -- it's generally not clinical studies anyway, but I believe in this case, none of them were done by FDA.
Q Yeah. It's very, very rare for the FDA to actually conduct its own clinical studies for --
A Oh, yes.
Q -- a new drug application?
A Yes.
Q Okay. New subject. I want to talk about just the drug in general. You went to medical school?
A Yes.
Q Got a doctor's degree?

A Yes.
Q You worked at the FDA?
A Yes.
Q You consult now with drug companies?
A Yes.
Q You would agree with me as a general principle that if you change brain chemistry, it has potential to lead to behavioral changes, right?
A Yes.
Q And there's a whole class of drugs that are geared toward changing brain chemistry to help behavior changes, right?
A Yes.
Q There are mood elevators, antidepressants, lots of drugs that work on brain chemistry trying to change the -- the way people are functioning behaviorally, fair?
A Yes.
Q All right. By the same token, you would agree with me as a scientific principle or medical principle, that a decrease in serotonin and norepinephrine levels can lead or be associated with, I should say, psychotic events?
MR. SAYLER: Objection, overly broad --
THE WITNESS: Now, I think that you're --

MR. SAYLER: -- misstates the facts.
THE WITNESS: -- you know, you really need to talk to a neurochemist if you are going to start talking about mechanism of action of the drug and neurochemistry. I have not -- I haven't been asked to --
Q I just left your area?
A Yeah.
Q Okay. Fair enough. I appreciate that. So you don't know whether or not a decrease in serotonin and norepinephrine has been associated with --
A You know, I think that --
Q Excuse me.
A -- you didn't hear me in the first place.
Q Excuse me. You cannot talk over me, ma'am.
A All right.
Q So you're not in a position to testify about whether or not a decrease in serotonin or norepinephrine would be associated with psychotic events; that's outside your area?
A It's not that it's -- I'm not -- I have not been asked to discuss anything besides the record and I think that if you need an expert

witness to do neurochemistry with you, you feel that, you know, that's an area you want to go into, that's your option, but I'm not your person.
Q I don't feel a need for that because I've got experts to do that.
A Good.
Q I'm trying to figure out if the lady who wrote the section that said that gabapentin, the Neurontin drug, has more serious events that may limit its usefulness including depression, I'm trying to figure out if you knew at the time that a decrease in serotonin and norepinephrine might be associated with psychotic events?
MR. SAYLER: Objection, misstates facts.
THE WITNESS: Whether it is or not is not the way you'd get an answer to that question. And again, if you want to talk neurochemistry on a theoretical basis, I'm not your person.
BY MR. LANIER:
Q So you had no knowledge --
A No. That's -- no. You're distorting what I said.
Q Okay. Did you know at the time you reviewed this drug that a decrease in serotonin or norepinephrine levels might be associated somehow

with psychotic behavior?
MR. SAYLER: Objection.
THE WITNESS: I think that's irrelevant.
BY MR. LANIER:
Q You may think it's irrelevant. I don't. That's not our call. That will be the judge's call.
A Okay.
Q My question is just a simple one: Did you have in your brain at the time an association between decrease in serotonin and norepinephrine and psychotic events?
MR. SAYLER: Objection.
THE WITNESS: I probably at the time did, but I think that there's -- you know, again, you are oversimplifying again this area and if you want to get into details, I don't want to discuss this with you.
Q All right. Fair enough. So as a general --
A This would not be my approach. Okay?
Q Okay.
A Drugs have actions that are widespread and to select out one specific neurotransmitter and think you've got a handle on the mechanism of action of the drug or its adverse events is -- is -- takes

a lot of hubris, and I -- again, I choose not to go there with you, and so, you know, if you want an expert to discuss this with you, fine.
Q I'm not trying to go there and I'm certainly not trying to be "Johnny Hubris" or make you "Sally Hubris." Okay. All I'm trying to do is, I would assume that when you're doing a review, you've got kind of red flags or cautions or ideas that -- that come up that you keep in your brain to be on the lookout for. Am I right or wrong in that?
A I think that you probably don't have a good feel for what's entailed in an FDA review. Sure, there are a lot of factors you consider, but frankly, you know, at an early stage -- at this -- at the early stage with this drug, the mechanism of action was not known, although a lot of potential mechanisms were considered, and whether or not the putative mechanism of action that would have been put forth was the correct one is irrelevant, because what really matters are the data and that's what you make your decisions upon, the clinical data.
MR. LANIER: Objection, nonresponsive.
THE WITNESS: No. That was quite responsive, actually.
BY MR. LANIER:

Q No, ma'am. You put in a bunch of stuff I wasn't talking about. I wasn't even talking about this drug.
A Well, you should have been --
Q No. That's --
A Because --
Q I promise you, I do my job pretty good. I'm not some schlock lawyer. I've actually done this before.
A Well, I don't care whether you're a schlock lawyer or not, but --
Q Okay. Well, then --
A -- we are here to discuss this drug in this application and, you know --
Q But in the process --
A -- if you want to discuss general neurochemistry and think great thoughts, go get yourself an expert.
Q Okay. Ma'am, just calm down. In the process --
A I'm calm.
Q In the process, I've got to ask some background information, sometimes they're tough questions. If you don't feel qualified to answer them, just tell me, "Mark, I'm not qualified to

an example. Before you wrote those prescriptions, did you run clinical trials, yourself --
A No.
Q -- on those drugs?
A No.
Q Before you wrote those drugs off-label, did you go out and do any epidemiological studies?
A No.
Q Did you do any randomized clinical trials?
A No. There had been trials done by other investigators in -- in pediatrics and, you know, I guess that's what I'm saying, that when a -- you know, a medical specialty decides to explore the use of a drug in a condition, it's not infrequent that that -- that investigators in that field might explore the dosing and the -- you know, the effect of that drug in that population, and oftentimes that will lead to further off-label use.

You know, as I said, most of the drugs that are approved for -- in the United States in the past have not been approved in pediatrics, so pediatricians have had little choice but to either extrapolate from the adult experience and rely upon the investigators in pediatrics to help to define what the parameters of dosing are and so on.

So there's a lot of -- I guess acceptance in the medical community that when a drug is approved, you don't know everything about it, that that information base will evolve over time, hopefully, this will lead to the company seeking -- doing further formal studies and seeking an indication, but that's not always the case, and certainly has not been the case in pediatrics.

MR. LANIER: Objection, nonresponsive.

BY MR. LANIER:
Q Ma'am, my question was simple --
A I thought it was quite responsive, actually.
Q Okay. Well, I'm missing it, because here was my question -- and we can go back and reread it, but word for word, it was this: Before you prescribed those drugs, did you do randomized clinical trials?

And you are talking to me about all sorts of things; I just want to know, did you?
A No, I did not.
Q Oh, okay. Thank you.

MR. SAYLER: Do you want to take a break?

MR. LANIER: I think I am almost done, if I can -- I'm either passing the witness or I'm going

to ask one more question. If you want to take a break, let's take a break because I've got describes right --

THE WITNESS: Thank you.

MR. LANIER: -- encyclopedic questions.

THE VIDEOGRAPHER: Off the record 10:57 a.m.

(Recess 10:57 a.m. to 11:15 a.m.)

THE VIDEOGRAPHER: On the record 11:15 a.m. This begins Tape 2 of the deposition.

EXAMINATION BY COUNSEL FOR PFIZER DEFENDANTS

BY MR. SAYLER:
Q Good morning, Dr. McCormick.
A Good morning.
Q I would like to begin by clarifying when you were employed by the FDA what your titles and general responsibilities were. When were you first employed at the FDA?
A 1991; I believe it was July that I started.
Q When did you leave the FDA?
A October of 2002.
Q From July of 1991 to October of 2002, were you continuously employed by the FDA?
A Yes.

Q What were your titles while you were employed at the FDA from 1991 to 2002?
A My initial title was medical officer and that was designated by series -- a series. Any -- any physician for the most part was -- was designated as a medical officer. I was not initially in a supervisory position, so basically it was medical officer and then the informal title was clinical reviewer or medical reviewer.

Subsequently, I was promoted to a supervisory medical officer and the informal title was division director, Division of Anesthetics, Critical Care and Addiction Drug Products.
Q How long were you in the first role of being a medical officer?
A About five years.
Q So from, roughly, 1991 to '96, '97?
A Yes. Uh-huh.
Q What were your general responsibilities as a medical officer?
A The review of investigational new drug applications.

THE WITNESS: I wonder if you could put the BlackBerry down. It's a little bit distracting. Thank you.

MR. LANIER: Well, this is the way I'm communicating with my expert on the phone. I'm sorry. I'll try and do it under the table. Would that be better?
THE WITNESS: Yes.
MR. LANIER: Okay. I don't mean to distract you.
A The question is --
BY MR. SAYLER:
Q You were talking about your responsibilities during your six or so years as a medical officer.
A Okay. Initially, review of applications that came in called "IND"s, or Investigational New Drug Applications or Exemptions to study drugs that were not -- that are not approved to do clinical trials in -- in human beings to explore new indications. Some of those were submitted by companies, some of them were submitted by individual investigators, to determine if a drug might have usefulness in a new indication or an off-label use.
THE REPORTER: Or a what?
MR. LANIER: An off-label use.
THE WITNESS: Off-label use.
THE REPORTER: Speak up a little.

THE WITNESS: I'm sorry.
A And so in addition to that, all of the responsibilities that an IND application carried with it, which would be attending meetings, reviewing safety reports that came in, clinical study reports and a whole host of responsibilities that went along with shepherding a drug through that process prior to approval. In addition --
BY MR. SAYLER:
Q Okay. So would that -- would that scope of responsibilities then fall under the umbrella of your IND review responsibilities?
A Right. That's right.
Q What were your other responsibilities as a medical officer?
A And let me just state that the -- my responsibilities at the time as a medical officer extended to epilepsy drugs, sleep drugs, drugs that were under investigation by the army and neuropathic pain. I also had some assorted INDs that overlapped with other conditions, but that was the bolus of what I had.
In addition to that, there were occasional consults that were -- that I was assigned to, some of which were consults to other parts of the agency

that may have involved epilepsy drugs, for example, issues that came up around those, and then finally, the review of I -- of NDAs, new drug applications.
Q So new drug application review was another element of your medical officer responsibilities --
A Right.
Q -- is that right?
THE WITNESS: That's correct.
MR. LANIER: Objection, leading.
BY MR. SAYLER:
Q Was it within the context of those responsibilities, IND review responsibilities or NDA review responsibilities that you performed your work in the first six years you were at the FDA with regard to Neurontin?
A I'm sorry. I was still listening to his comment.
Q Well, was it as part of your NDA review responsibilities that you performed your work with respect to Neurontin during those first six years you were at the FDA?
A Yes, initially. I saw Neurontin again later in my subsequent responsibilities.
Q And I want to get to that.
A Okay.

Q Okay. So after you were a medical officer for approximately six years, you then were promoted to a division director --
A Correct.
Q -- title or role, correct?
A Correct.
Q Okay. What were your roles and responsibilities as division director from approximately 1996 to the -- the end of your tenure at FDA in 2002?
A The responsibilities were basically supervising all aspects of the portfolio within that division both under the investigational new drug application, consults to other divisions, and new drug applications for all of the drugs that were in our portfolio which included anesthetics. We had for a period of time responsibility for drug scheduling recommendations, abuse liability evaluation, drugs of addiction and pain medications, and as well as consulting to other parts of the agency.
Then I was on some committees, as well, and, you know, that basically -- I mean, we could go into more detail on what that meant, what that entailed, but basically, a review team consists of a

group of people who are assigned from various specialties to -- to the review and evaluation of data or -- or proposals, protocols, and so on, and the team consisted of chemists and toxicologists, biopharmaceutics experts, clinicians and statisticians and project managers. Not all of those were under my direct supervisory responsibility in terms of performance, however, the performance of the team at large was my responsibility; and I also had direct responsibility for drug approval for certain types of applications that were not primarily new molecular entities but reformulations, that sort of things, or new indications.

Q We'll get into it in more detail, but was it in your role as division director that you were involved in the review and the ultimate approval of Neurontin as a treatment for post-herpetic neuralgia in the spring of 2002?

A Yes.

Q Dr. McCormick, while you were at the FDA from 1991 to 2002, did you ever conclude that Neurontin increases the risk of or is causally associated with depression?

MR. FINKELSTEIN: Objection.

MR. LANIER: Objection, form.

THE WITNESS: Did I ever conclude that it was causally related? No, I did not.

BY MR. SAYLER:

Q While you were employed at the FDA from 1991 to 2002, did you ever conclude that Neurontin increases the risk of or is causally associated with any type of suicidal thinking or suicidal behavior?

MR. FINKELSTEIN: Objection --

MR. LANIER: Objection, form.

MR. FINKELSTEIN: -- form.

THE WITNESS: In the documents that I reviewed, both in my responsibility as a medical officer in epilepsy and also in my review of the Neurontin application for post-herpetic neuralgia, I did not see anything that would suggest an increased risk of suicidality.

MR. LANIER: Objection, responsiveness.

BY MR. SAYLER:

Q To this day, as you sit here today taking into account everything you know, have you ever reached a conclusion that Neurontin increases the risk of or is causally associated with depression, any other psychiatric adverse event, or any type of suicidal thinking or behavior?

MR. LANIER: Objection, form.

MR. FINKELSTEIN: Objection.

THE WITNESS: I have not. I have to say that the recent FDA Alert that I am aware of states that there is a risk of increased suicidality with the initiation of anticonvulsants in general, and I have not seen the data myself. I have seen some data on -- I have seen the data on Neurontin from the -- the marketing applications, and the two don't comport with each other. I think that, you know, they may have more data than I do.

BY MR. SAYLER:

Q Again, back to my question with respect to Neurontin specifically: As you sit here today, have you ever concluded that Neurontin increases the risk of or causes any type of suicidal thinking or behavior?

MR. LANIER: Objection, form.

MR. FINKELSTEIN: Objection, form.

THE WITNESS: Affirmatively concluded, no. I have not affirmatively concluded that it does either.

BY MR. SAYLER:

Q While you were at the FDA, to the best of your knowledge, did any individual within the FDA or

the FDA generally, ever conclude that Neurontin is associated with or increases the risk of depression or any type of suicidal thinking or behavior?

MR. FINKELSTEIN: Objection, form.

THE WITNESS: No. I mean, if it had -- if we had, we would have put it in the label.

MR. LANIER: Objection, responsiveness.

BY MR. SAYLER:

Q If FDA had concluded that Neurontin increased the risk of depression or any type of suicidal thinking or behavior, what based on your experience would the FDA had done?

MR. FINKELSTEIN: Objection.

THE WITNESS: If we had -- I'm sorry.

MR. FINKELSTEIN: Objection, calls for speculation, but you can answer it.

MR. SAYLER: Go ahead.

MR. FINKELSTEIN: Go ahead.

THE WITNESS: Well, you know, I -- you know, we can -- you can call it speculation, but I was in a position to do something, so it's not really speculative.

I think that, you know, the first -- the first opportunity was when the NDA was reviewed in the first place and presented to the advisory

Deposition Exhibit 12. Do you see that this is a document dated March 21, 2005, with the "Finkelstein & Partners" letterhead at the top of the first page?
A Yes.
Q And do you see that the -- this appears to be a letter to a Dr. Russell Katz, Director of Neuropharmacological Drug Products Division of the Food and Drug Administration?
A Right. Yes.
Q And you see the signature on the last page of "Andrew G. Finkelstein"; do you see that?
A Yes.
Q I want to direct your attention to the third paragraph on the first page of this letter. It states:
Recently we obtained the FDA's analysis of the new drug application filed by Parke-Davis and found shocking information during your -- meaning FDA's -- during your evaluation of serious adverse events that occurred during original clinical trials, the risk of Neurontin causing suicide was both known and a major concern. The FDA clinical reviewer from your division specifically stated in December 1992 serious adverse events may limit the drug's widespread usefulness. Depression, while it

may not be an infrequent occurrence in the epileptic population, may become worse and require intervention or lead to suicide as it has resulted in some suicidal attempts during clinical trials.
Did I read that correctly?
A Yes.
Q And do you recognize that the clinical review language being quoted there is the language that comes from your medical review that you did in 1992?
A Yes, with the emphasis added, by the person who wrote the letter.
Q Do you agree with the characterization of your words that these -- these words establish that the risk of Neurontin causing suicide was known and a major concern; stated otherwise, in -- in those words, are you intending to state that you believe Neurontin causes suicide?
MR. LANIER: Objection, form.
THE WITNESS: No. I think that it doesn't say that at all. What it says is that while depression is an infrequent occur -- it's not an infrequent occurring with this -- common in this population, particularly in the complex partial seizure population, in the context of the clinical

trial with -- particularly in the uncontrolled database, there were patients who got worse and required treatment. There were some people who -- I mean, basically the numbers that you see in the review are the treatment emergent depression -- treatment emergent adverse events in general, those are patients who either had new onset or worsening of their symptoms during the clinical trial and, you know, as a general statement, yes, depression can sometimes lead to suicide. It doesn't say that Neurontin causes suicide.
MR. LANIER: Objection, nonresponsive.
Q While you were at the FDA -- while you were at the FDA, did you ever conclude or intend to suggest that you believe Neurontin causes suicide?
A No, never.
Q Do you believe that this letter accurately characterizes your intentions and your statements?
THE WITNESS: No.
MR. LANIER: Objection.
BY MR. SAYLER:
Q Did Mr. Finkelstein or anybody else --
A I mean, let me just elaborate. The risk of Neurontin causing suicide was known and a major concern is simply not true.

Q Did Mr. Finkelstein or anybody else affiliated with Mr. Finkelstein ever contact you and say: Hey, we are going to send a letter to the FDA stating that your words establish your belief that Neurontin causes suicide; would that be an accurate statement?
A They didn't contact me.
Q Were you ever contacted with that question?
A No.
Q Has anybody from Mr. Finkelstein's firm or Mr. Finkelstein himself ever contacted you and asked you to sit down and discuss your analyses and your findings during the time you were at the FDA?
A While I was at the FDA, no.
Q No. Has --
A Or my findings at the FDA --
Q Has anybody ever from Mr. Finkelstein's firm --
A No.
Q -- ever contacted you and said I'd like to sit down and talk to you about what you have concluded?
A No, not that I'm aware. I mean, I have to say that I get random calls from -- from attorneys

A Zero.
Q Next is preparatory acts; which code would that be?
A Code three.
Q How many preparatory acts toward imminent suicide behavior were there in the gabapentin population?
A Zero.
Q And then finally is suicidal ideation; which code would that be?
A Code five.
Q And how many cases of suicidal ideation were there in the gabapentin population?
A There were two.
Q And how many -- and what percentage did that add up to?
A .039 percent.
Q .039 percent?
A Uh-huh.
Q And how many cases of suicidal ideation were there in the placebo population?
A There was one.
Q And what percentage did that add up to?
A .037.
Q Now, the FDA Alert states that when this

data is pooled for all 11 antiepileptic drugs, we have a -- a incidence of 0.43 percent in the pooled drug population versus an incidence of 0.22 percent in the placebo population.
Do you see that --
A Yes, I do.
Q -- in the FDA's alert?
A Yes, I do.
Q Whereas, if we look at the data in the gabapentin-only population and we add up the percentages in codes one, two, three and five, what are the percentages in gabapentin versus placebo?
A Sorry. So one, two, three, four and five?
Q One, two, three and five.
A One, two, three and five. Well, it's still two -- .037 -- .039 percent, because there's a zero in the other categories.
MR. FINKELSTEIN: I just want to object to this whole line of questioning and set forth that at no point in time has Dr. McCormick ever been put forth as an expert and it seems that you are seeking to elicit expert testimony. You can go forward with your line of questioning. I'm just reserving my right to make the appropriate application related to it.

BY MR. SAYLER:
Q You testified earlier that the FDA Alert does not change as you sit here today the fact that you have never concluded that Neurontin increases the risk of or causes suicide-related behavior; is that your testimony?
MR. LANIER: Objection, form.
THE WITNESS: That's correct.
BY MR. SAYLER:
Q And can you --
A That's correct. I mean, these data are largely --
Q Let me ask a question.
A Okay.
Q Can you -- can you explain why your conclusion has not changed as you sit here today notwithstanding the FDA Alert?
MR. FINKELSTEIN: Objection.
THE WITNESS: Because the -- there was no signal in the controlled database in both NDAs. This is simply -- this is basically the same data.
BY MR. SAYLER:
Q And when you say "both NDAs," you are talking about --
A Both, the NDA and --

Q -- Neurontin NDAs?
A -- and the SNDA, the supplemental NDA for a new indication.
This is basically the same data. You know, I have some -- some problems with the way this was done taking into account the -- I mean, even if you were to take out the post-herpetic neuralgia and look at just the epilepsy. Let's assume for a minute that -- you know, that this is going to, you know, tighten up the analysis. The numbers are only going to get smaller. It's hard to get much smaller than two or one, but in the controlled database there just is no signal. There was not then and there still isn't; no surprise, it's the same data.
Q How does the analysis contained in the June 2006 submission marked as Deposition Exhibit 13, how does that affect the fact that you never concluded that Neurontin increases the risk of or causes suicide-related behavior?
MR. LANIER: Objection, form.
THE WITNESS: It reinforces it. It reinforces it. You know, this tells me that something else is driving this analysis. We obviously don't have a full analysis, because it doesn't -- they don't -- these documents don't talk